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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,872	02/21/2002	Walter Callen	564462006100	9897

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DIVERSA C/O MOFO S.D.
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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,872	CALLEN ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *74,108,112-116,118-121 and 147-166* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-12, 14-17, 47, 48, 75-80, 84-86, 88, 89, 92, 102-107, 122-146* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-12,14-17,47,48,74-80,84-86,88,89,92,102-108,112-116 and 118-166.

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/06 has been entered.

Claims 5, 13, 18-46, 49-73, 81-83, 87, 90-91, 93-101, 109-111, and 117 have been canceled. Claims 1-4, 6-12, 14-17, 47, 48, 74-80, 84-86, 88, 89, 92, 102-108, 112-116, 118-135 and newly presented claims 136-166 are still at issue and are present for examination.

Claims 74, 108, 112-116 and 118-121 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the response filed 6/23/03. Newly presented claims 147-166 recite methods which are patentably distinct from the elected group as the nucleic acids of the elected group are neither made nor used by the methods of Claims 147-166. As such all of claims 147-166 are withdrawn herein.

Claims 1-4, 6-12, 14-17, 47, 48, 75-80, 84-86, 88, 89, 92, 102-107, 122-135 and newly presented claims 136-146 are examined herein.

Claims 1-4, 6-12, 14-17, 48, 75-80, 84-86, 88, 89, 92, 102-107, 124-128, and 131-146 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 10-12, and 143 (upon which claims 4, 6-9, 14-17, 48, 102-107, 125-127, 131-142, and 144-146 depend) are indefinite in the recitation of "sequences complementary to" a reference sequence as it is unclear if this term includes only the full length complement of the reference sequence or encompasses sequences complementary to only a portion of the reference sequence. For purposes of further examination it is presumed that this was intended to only include the complement of the full length sequence.

Claim 8 is indefinite in the recitation of 99% identity to SEQ ID NO:126 over a region of at least 75 consecutive residues" as a single change within a region of only 75 residues would lead to a % sequence identity of less than 99%.

Claims 10-11 (upon which claims 132, and 138-142 depend) is confusing in the recitation of "encoding a polypeptide having

alpha amylase activity consisting of a sequence having at least 98% sequence identity to 150 consecutive amino acid residues of SEQ ID NO:126" in Claim 10 or "encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 99% sequence identity to 100 consecutive amino acid residues of SEQ ID NO:126" as there is no indication that any polypeptide fragment of SEQ ID NO:126 of only 100 or 150 amino acids in length has alpha amylase activity such that there appears to be no such sequences.

Claim 12 (upon which claims 133, and 136-142 depend) is confusing in the recitation "encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 90% sequence identity to about 300 consecutive residues of SEQ ID NO:125" as there is no indication that any fragment of SEQ ID NO:125 of only 300 nucleotides in length encodes a peptide having alpha amylase activity such that there appears to be no such sequences.

Claim 75 (upon which claims 76-80, 84-86, 88, 89 and 92 depend) is confusing in the recitation of "A probe **comprising** an oligonucleotide **consisting of**" as the conjunction of both open and closed language makes it unclear what is intended. For purposes of examination the claim is read as open.

Claim 124 is confusing in the recitation of "wherein the sequence identity is determined comprising use of a BLASTN or BLASTP algorithm" as the only sequence identity recited in Claim 47 (from which claim 124 depends is amino acid sequence identity but BLASTN is an algorithm for determining identity of nucleic acid sequences.

Claim 125 is confusing in the recitation of "wherein the polypeptide having alpha amylase activity has a sequence having at least 96% identity to SEQ ID NO:125 over a region of at least 150 consecutive nucleotides" as proteins do not comprise nucleic acid sequences.

Claim 126 and 127 are confusing in the recitation of "wherein the sequence encoding the polypeptide has at least 98% (or 99%) identity to SEQ ID NO:126 over a region of at least 150 consecutive amino acid residues" as nucleic acids do not comprise amino acid sequences.

Claims 136 and 137 are confusing in the recitation of "the nucleic acid of claim 12, wher3ein in step (a) the sequence encodes a polypeptide having alpha amylase activity consisting of a sequence having at least 90% sequence identity to about 400 (or 500) consecutive residues of SEQ ID NO:125" as claim 12 recites "encoding a polypeptide having alpha amylase activity consisting of a sequence having at least 90% sequence identity

to about 300 consecutive residues of SEQ ID NO:125". The same sequence cannot consist of about 300 nucleotides and about 400 (or 500) nucleotides. Note the language "consisting of excludes additional sequence.

Claims 1, 2 and 143 (upon which claims 4, 6-9, 14-17, 48, 102-107, 125-127, 131, 134 and 144-146 depend) are confusing in the recitation of "a sequence encoding a polypeptide having alpha amylase activity, wherein the sequence has at least 90% (or 95%) sequence identity to SEQ ID NO:126" as nucleic acids do not comprise amino acid sequences.

Claim 128 is confusing in the recitation "wherein the probe can identify or isolate an amylase-encoding gene by hybridizing to the gene..." as it is unclear how one can distinguish functional capabilities of a nucleic acid by hybridization as hybridization is a purely structural phenomenon; i.e., hybridization occurs between any two nucleic acids which are sufficiently similar to each other to bind under the conditions of the hybridization reaction. Since even single changes to a nucleic acid sequence can result in the loss of activity of the encoded protein and conversely very different sequences structurally can encode proteins having the same activity it is unclear how an alpha amylase encoding gene can be distinguished from all sequences which do not encode an alpha amylase merely

by hybridization. As such the recitation "identify or isolate an amylase-encoding gene by" has been given no patentable weight.

Claims 10-12, 17, 75-80, 84-86, 88, 89, 92, 128, 129, 132-133 and 136-142 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is explained in the previous Office Action.

Applicants argue that the amendment of claims 10-12 to alter "comprising" to consisting of corrects the examiner's previous concern that that recited structural features were not correlated with recited functional features. However, this is not persuasive because the amendment merely creates the additional problem that the application teaches **NO** representative species of any sequences within these claims as the specification does not teach any portion of the protein of SEQ ID NO:126 of 100-150 amino acids in length that has alpha amylase activity. Since the claim has been amended to recite "consisting of" these claims are now limited to nucleic acids encoding alpha amylases of 100 or 150 amino acids in length

having at least 90% identity to 100 or 150 amino acids of SEQ ID N:126.

Applicants argue that the amendment of claims 17, 75 128, and 129 corrects the examiner's previous concern that that some of the claims have no functional limitation. However, this is not persuasive as the recitation that the probe "hybridizes to SEQ ID NO:125" is not a functional limitation as hybridization is a purely structural phenomenon; i.e., hybridization occurs between any two nucleic acids which are sufficiently similar to each other to bind under the conditions of the hybridization reaction. Even single changes to a nucleic acid sequence can result in the loss of activity of the encoded protein and conversely very different sequences structurally can encode proteins having the same activity. As such the recitation in the instant claims is purely structural in nature. An alpha amylase encoding gene can not be distinguished from all sequences which do not encode an alpha amylase merely by hybridization.

Claims 1, 6-12, 16, 17, 47, 48, 75-80, 84-86, 88, 89, 92, 122-130, 132, 133 and 136-142 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding SEQ ID NO:126, does not reasonably provide enablement for any polynucleotide having at least 85%

sequence identity to SEQ ID NO:125 and encoding a polypeptide with an alpha amylase activity or any polynucleotide comprising at least 50-500 bases of a sequence having 90-99% identity to SEQ ID NO:125, or any polynucleotide comprising a fragment of SEQ ID NO:125, or all fragments and variants thereof or vectors and host cells comprising said nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants argue that it is not necessary that the specification or the state of the art at the time of the invention describe a protocol where every, or even most, attempts at making a nucleic acid within the limitations of the claimed invention are successful. Because the proper legal test is that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims methods for making the claimed genera of amylase-encoding nucleic acids are sufficiently enabling if a reasonable number of species are successfully made by protocols known in the art and/or described in the specification. However, this is not persuasive as the law clearly requires that the specification teach one or ordinary skill in the art to make and use the entire scope of

the invention claimed. While it is acknowledged that this does not require that the specification or the state of the art at the time of the invention describe how to make and use **every** species within the scope of the claims it does clearly require a "reasonable correlation" to the scope of the claims. For all the reasons which have been extensively discussed in the previous Office Actions, the instant specification does not even begin scratch the surface of teaching how to make any use even a reasonable portion of the scope of the rejected claims and thus a "reasonable correlation" to the scope of the claims has not been provided. As such the rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75, 76, 84-85, and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana et al. (Reference AK of applicant's IDS).

Tachibana et al. teach the isolation and expression of a polynucleotide encoding *Pyrococcus* sp. KOD1 alpha amylase. This polynucleotide has 80% identity to SEQ ID NO:125 and encodes a protein with 85% identity to SEQ ID NO:126. Furthermore, while

the entire gene of Tachibana et al. does not have 85% identity to the entire sequence of SEQ ID NO:125, it comprises a region of 75 nucleotides having greater than 85% identity to the corresponding portion of SEQ ID NO:125 (i.e., residues 1463-1537 of Tachibana et al. have 93% identity to residues 1018-1092 of SEQ ID NO:125) and thus anticipate claims 75, 76, 84-85, and 92.

Applicants argue that the rejection is improper as Tachibana et al. sequence does not encode a nucleic acid that has greater than 95% identity over 75 nucleotides to SEQ ID NO125. However, this is not a requirement of the instant claims. The instant claims recite nucleic acids comprising a sequence of at least 75 nucleotides of a nucleic acid of claim 2 (ie.e, encoding an alpha amylase and having 85% identity to SEQ ID NO:125). Tachibana et al. clearly do recite a nucleic acid 75 nucleotides of a nucleic acid of claim 2.

Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana et al. (Reference AK). The rejection is explained in the previous Office Action.

Applicant has not presented any arguments specifically traversing this rejection but instead relies upon the traversal discussed above. Therefore, this rejection is maintained for the reasons presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Prouty
Primary Examiner
Art Unit 1652